

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILI	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,382	10/	/09/2001	Warren Heston	D6230	5861
7.	590	03/25/2003			
Benjamin Aar			EXAMINER		
ADLER & ASS 8011 Candle La		ES		DAVIS, MINI	Н ТАМ В
*	Houston, TX 77071				
····,				ART UNIT	PAPER NUMBER
				1642	
			DATE MAILED: 03/25/2003		Ś

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	on N .	Applicant(s)				
		09/973,38	32	HESTON ET AL.				
	Office Action Summary	Examiner		Art Unit				
		MINH-TAN	M DAVIS	1642				
	The MAILING DATE of this communication a	ppears on the	cover sheet with the c	orrespondence address				
Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status								
1)🖂								
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ 1	This action is	non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
·	on of Claims							
· ·	4) Claim(s) 1-42 is/are pending in the application.							
	4a) Of the above claim(s) is/are withdr	rawn from co	nsideration.					
	5) Claim(s) is/are allowed.							
	6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.								
-	Claim(s) <u>1-42</u> are subject to restriction and/o on Papers	r election rec	juirement.					
·· _	9) The specification is objected to by the Examiner.							
-	10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12)☐ The oath or declaration is objected to by the Examiner.								
Priority u	ınder 35 U.S.C. §§ 119 and 120							
13)	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)[	a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
	4) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a	a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)								
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	)		y (PTO-413) Paper No(s) Patent Application (PTO-152)				

Application/Control Number: 09/973,382 Page 2

Art Unit: 1642

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a DNA fragment encoding a mammalian prostate specific membrane antigen-like protein, or SEQ ID NO:1, a vector comprising said fragment, and a host cell transfected with said vector, classified in class 536, subclass 23.1.
- II. Claims 8-9, drawn to a prostate specific membrane antigen-like protein, or SEQ ID NO:2, or a fragment thereof, classified in class 530, subclass 350.
- III. Claims 10, 30-32, drawn to an antibody directed against a prostate specific membrane antigen-like protein, or SEQ ID NO:2, and a cytotoxic composition comprising a compound specific for a prostate specific membrane antigen-like protein, or a fragment thereof, and a cytotoxic agent, classified in class 530, subclass 387.1.
- IV. Claims 11-16, drawn to a method for distinguishing prostate specific membrane antigen gene expression from prostate specific membrane antigen-like gene expression, comprising producing RT-PCR products and detecting the predicted fragments produced after exposure of said RT-PCT products to a restriction enzyme, classified in class 435, subclass 6.
- V. Claims 17-21, drawn to a method for distinguishing prostate specific membrane antigen gene expression from prostate specific membrane antigen-like gene expression, comprising detecting binding of at least one antibody specific for a prostate specific membrane antigen protein and/or at least one antibody specific for a prostate specific membrane antigen-like protein, classified in class 435, subclass 7.1.

Art Unit: 1642

- VI. Claims 22-23, drawn to a vector for targeted gene therapy, comprising a promoter/enhancer of a prostate specific membrane antigen gene, classified in class 435, subclass 320.1.
- VII. Claims 22-23, drawn to a vector for targeted gene therapy, comprising a promoter/enhancer of a prostate specific membrane antigen-like gene, classified in class 435, subclass 320.1.
- VIII. Claim 24, drawn to a method for screening prostate specific membrane antigenlike ligands, classified in class 435, subclass 7.1.
- IX. Claim 25, drawn to a method for screening prostate specific membrane antigen ligands, classified in class 435, subclass 7.1.
- X. Claims 26-27, drawn to a method for imaging cells expressing a prostate specific membrane antigen-like protein, classified in class 435, subclass 7.1.
- XI. Claims 28-29, drawn to a method for imaging cells expressing a prostate specific membrane antigen protein, classified in class 435, subclass 7.1.
- XII. Claims 30-33, a pharmaceutical composition comprising an antibody directed against a prostate specific membrane antigen protein, or a cytotoxic composition comprising a compound specific for a prostate specific membrane antigen protein and a cytotoxic agent, classified in class 530, subclass 350.
- XIII. Claims 34-35, drawn to a method for detecting prostate cancer, classified in class 435, subclass 7.1.
- XIV. Claims 34-35, drawn to a method for detecting bladder cancer, classified in class 435, subclass 7.1.

Art Unit: 1642

XV. Claims 34-35, drawn to a method for detecting a sarcoma, classified in class 435, subclass 7.1.

XVI. Claims 34-35, drawn to a method for detecting melanoma cancer, classified in class 435, subclass 7.1.

XVII. Claims 34-35, drawn to a method for detecting a melanoma, classified in class 435, subclass 7.1.

XVIII. Claims 34-35, drawn to a method for detecting a lung cancer, classified in class 435, subclass 7.1.

XIX. Claims 34-35, drawn to a method for detecting a kidney cancer, classified in class 435, subclass 7.1.

XX. Claims 36-37, drawn to a method for detecting a neurological disorder, classified in class 435, subclass 7.1.

XXI. Claims 38-40, drawn to a method for inducing cell death, using a vector expressing PSMA-like protein, classified in class 514, subclass 44.

XXII. Claims 41-42, drawn to a method for inhibiting cell death, comprising administering an inhibitor of PSMA-like protein, classified in class 514, subclass 2.

In addition, upon election of group III, further election of the following patentably distinct species:

A ligand or an antibody or a cytotoxic compound, wherein a ligand is generic to an antibody.

Upon election of group IV, further election of the following patentably distinct species:

Art Unit: 1642

Any one of the samples recited in claim 13.

Any one of the restriction enzymes recited in claim 14.

Upon election of group V, further election of the following patentably distinct species:

Any one of the samples recited in claim 18.

Upon election of any of groups X-XI, further election of the following patentably distinct species:

A ligand or an antibody, wherein a ligand is generic to an antibody.

The inventions are distinct, each from each other because of the following reasons:

Inventions (I-III, VI-VII, XII) and (IV-V, VII-XI, XIII-XXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; a vector could be used for expressing a gene, for testing drugs and for gene therapy, and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

Art Unit: 1642

The products of groups I-III, VI-VII, XII are patentably distinct, because they are drawn to entirely different biochemicals, having different structures, biological properties and activities.

The methods of groups IV-V, VII-XI, XIII-XXII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species a ligand or an antibody or a cytotoxic compound are distinct because they have different structure.

The species samples are different because they have different properties.

The species restriction are different because they have different properties.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and further, because the searches for the groups are not coextensive, and therefore, it would be a serious burden for the Examiner to examine all the groups and species together, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Art Unit: 1642

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

Application/Control Number: 09/973,382 Page 8

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

March 21, 2003

SUSAN UNGAR, PH.D PRIMARY EXAMINER